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DIVISION OF PUBLIC HEALTH

BUREAU OF ENVIRONMENTAL HEALTH
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State of Wisconsin
Department of Health and Family Services

May 12, 1999

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

To Whom It May Concern:

This comment is in response to *THE MAMMOGRAPHY QUALITY STANDARDS ACT FINAL REGULATIONS GOOD GUIDANCE PRACTICE DOCUMENT #2*: "How often must the densitometer and sensitometer be calibrated? What should the facility do while they are out being serviced or while they are broken?"

Specifically, the second half of the above question is of concern. The State of Wisconsin feels there could be a more common sense interpretation to this question other than the facility have back up equipment available. I am not aware of many facilities having extra equipment sitting around to use "just in case." This GGP #2 issue makes it almost impossible for many of our facilities to operate especially those in rural surroundings. We are concerned many qualified MQSA Certified Facilities will act against this issue and/or will rely on our inspectors to be understanding or look the other way in this particular instance.

Please rethink this issue and devise a method for allowing an acceptable alternative for this issue.

Sincerely,

Mark C. Bunge, Supervisor
Radiation Protection Section
Division of Public Health

STATE OF WISCONSIN

DEPARTMENT OF HEALTH & FAMILY SERVICES
DIVISION OF HEALTH
1 WEST WILSON STREET
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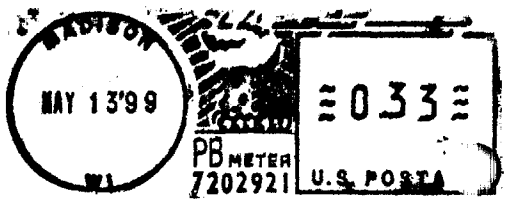
Return Service Requested



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